



## **First child vaccinated with Intercell Japanese Encephalitis (JE) Vaccine in India - Pediatric Phase II clinical trial started**

- » Development process for vaccine launch in endemic countries accelerated – First child vaccinated with IC51
- » First administration of Intercell's JE vaccine to children – Results of Phase II trial are expected in late 2007
- » Development plan for endemic regions clearly defined – Market launch expected in 2009

**Vienna (Austria), July 16, 2007** – Intercell AG and its partner Biological E. Ltd. (Hyderabad, India) announced today that the companies have started a pediatric Phase II clinical trial for Intercell's novel Japanese Encephalitis Vaccine in India.

The randomized and controlled study aims to demonstrate the dose, safety and immunogenicity of Intercell's JE vaccine compared to a locally available, Korean made mouse-brain Japanese Encephalitis vaccine. The study will enroll 60 children at the age of one to three years. It is the first step toward the licensure of a new cell culture derived product in Asia, which is expected in 2009.

"The start of the pediatric clinical trials in India is a major step forward to make our vaccine, which is based on a proven and safe technology, available also for the population, and especially the children, in endemic regions," states Gerd Zettlmeissl, Chief Executive Officer of Intercell AG.

Vijay Kumar Datla, Chairman and Managing Director of Biological E. Ltd added, "With the spirit and energy of this partnership we aim to make equitable access to this important intervention against JE available in the endemic regions of the world. This trial will be followed by a corresponding Phase III study in both children and adults in India."

### **About Intercell's investigational JE vaccine (IC51)**

Intercell's novel investigational JE vaccine is a purified, inactivated vaccine for active immunization against the Japanese Encephalitis virus. With over 3 billion people living in endemic areas, Japanese Encephalitis, a mosquito-borne flaviviral infection, is the leading cause of childhood encephalitis and viral encephalitis in Asia.

In successfully concluded pivotal **Phase III trials**, Intercell's Japanese Encephalitis vaccine (IC51) demonstrated a favorable safety and immunogenicity profile:

- » The immunogenicity of IC51 was at least as good as the U.S. licensed product, JE-VAX®
- » IC51 demonstrated an overall clinical safety profile similar to placebo
- » Further, IC51 showed an excellent local tolerability profile in this head-to-head study with JE-VAX®



Intercell's novel JE vaccine, manufactured in the company's proprietary manufacturing facility in Scotland, is prepared using tissue culture rather than live organisms and, unlike JE-VAX®, does not contain any stabilizers such as gelatin or preservatives in its formulation.

On June 13, 2006, Novartis and Intercell announced that the companies had reached an agreement for Novartis to acquire marketing and distribution rights for Intercell's Japanese Encephalitis Virus Vaccine in the United States, Europe and certain other markets in Asia and Latin America.

### **About Biological E. Ltd**

Over the last 50 years, Biological E. Ltd. (BE) has been a leading vaccine and pharmaceutical company. The company produces a range of critical vaccines and has been an active partner in the National Immunization Program of India. The company is currently commissioning large-scale cGMP facilities in order to increase its capacities and product range to offer these vaccines on a global basis. In addition to its current pipeline of combination vaccines that are entering pivotal trials, BE has R&D programs to develop novel vaccines for both vector-borne and enteric diseases. The company has entered into a number of strategic collaborations with leading biotech companies and research institutes for basic R&D. Biological E. is a privately held company. Biological E will manufacture Intercell's JE vaccine for the Asian markets and will exclusively market and distribute the product in India, Nepal, Bhutan and Bangladesh.

For more information please visit: [www.biologicale.com](http://www.biologicale.com)

### **About Intercell AG:**

Intercell AG is a growing biotechnology company which focuses on the design and development of novel vaccines for the prevention and treatment of infectious diseases with substantial unmet medical need. The Company develops antigens and adjuvants which are derived from its proprietary technology platforms, and has in-house GMP manufacturing capability. Based on these technologies, Intercell has strategic partnerships with a number of global pharmaceutical companies, including Novartis, Merck & Co., Inc., Wyeth, sanofi pasteur, Kirin and the Statens Serum Institut.

The Company's leading product, a prophylactic vaccine against Japanese Encephalitis, successfully concluded pivotal Phase III clinical trials in 2006. The regulatory process toward a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) has been initiated. The broad development pipeline includes a Pseudomonas vaccine in Phase II, a therapeutic vaccine for Hepatitis C in Phase II, partnered vaccines for Tuberculosis and Staphylococcus aureus which are in Phase I, and five products focused on infectious diseases in preclinical development. Intercell is listed on the Vienna stock exchange under the symbol "ICLL".

For more information please visit: [www.intercell.com](http://www.intercell.com)



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